

1 CLAIMS

2 I claim:

3 1. A method of orally immunizing a host organism against gastrointestinal, mucosally invasive
4 *Mycobacterium avium* subspecies *paratuberculosis*, the steps comprising:

5 a. providing an enteric, mucosally adherent, non-systemically invasive *Mycobacterium*
6 *avium* subspecies *paratuberculosis* organism;

7 b. orally administering the MAP organism to a host animal in an immunizing dose and
8 manner.

9 2. The method of claim 1, wherein the MAP organism stimulates Th1-type response and elicits
10 IgA secretion and cell-mediated immunity.

11 3. The method of claim 2, wherein the MAP is viable organism.

12 4. The method of claim 2, wherein the MAP is recombinant organism.

13 5. The method of claim 1, wherein the MAP is a non-protein denatured killed organism.

14 6. The method of claim 1, wherein the MAP target organ is intestinal mucosa.

15 7. A method for generating an enteric, mucosally adherent, non-systemically invasive, live
16 mucosal *Mycobacterium avium* subspecies *paratuberculosis* vaccine organism, the steps
17 comprising:

18 a) selecting mucosa-adherent MAP organism strain based on desired binding affinity to
19 an animal species' gastrointestinal tract;

20 b) serially passaging the MAP strain in culture and/or alien species sufficiently to alter
21 genomic expression;

22 c) monitoring the strain for adherence to the animal species' gastrointestinal tract;

23 d) demonstrating in-vivo attenuation of the MAP strain;

- 1 e) testing for the ability of the MAP strain to confer protection against mucosal challenge.
- 2 8. The method of claim 7, further including the step of adding mutagens in culture during serial
- 3 passage.
- 4 9. The method of claim 7, further including the step of monitoring for mucosal and systemic
- 5 invasiveness in host animals.
- 6 10. A mucosal vaccine against a gastrointestinally invasive *Mycobacterium avium* subspecies
- 7 paratuberculosis, comprising:
- 8 an enteric, mucosally-adherent, non-systemically invasive *Mycobacterium avium* subspecies
- 9 paratuberculosis organism and a pharmaceutically acceptable carrier.
- 10 11. The vaccine of claim 10, wherein the MAP organism stimulates a Th1-type response and
- 11 elicits IgA secretion and cell-mediated immunity.
- 12 12. The vaccine of claim 10, wherein the MAP is a viable organism.
- 13 13. The vaccine of claim 10, wherein the MAP is a recombinant organism.
- 14 14. The vaccine of claim 10, wherein the MAP is a non-protein denatured killed organism.
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